

IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

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BECTON, DICKINSON AND COMPANY,
GENEOHM SCIENCES CANADA, INC., : CIVIL ACTION
and HANDYLAB, INC., :
:
Plaintiffs, :
v :
:
NEUMODX MOLECULAR, INC, :
:
Defendant. : NO. 19-1126-LPS

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Wilmington, Delaware
Thursday, June 25, 2020
Telephonic Oral Argument

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BEFORE: HONORABLE LEONARD P. STARK, Chief Judge

APPEARANCES:

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23 P R O C E E D I N G S

24 (REPORTER'S NOTE: The following telephonic oral
25 argument hearing was held remotely, beginning at 1:34 p.m.)

1 THE COURT: Good afternoon, everybody. This is
2 Judge Stark. Who is there for the plaintiffs, please?

3 MR. FLYNN: Good afternoon, Your Honor. This is
4 Michael Flynn from Morris Nichols on behalf of plaintiffs.
5 And with me on the line is Omar Kahn and David Yin from
6 Wilmer Hale; and we also have Scott Rittman who is Chief
7 Counsel for Intellectual Property at Becton Dickinson and
8 Company.

9 THE COURT: Okay. Good afternoon to all of you.
10 And who is there for defendant, please?

11 MR. FARNAN: Good afternoon, Your Honor. Brian
12 Farnan on behalf of the defendant; and with me is James
13 Cleland and Michael Spink from Dickinson Wright.

14 THE COURT: Okay. Good afternoon to you all
15 as well. I have a court reporter, of course, taking
16 everything down; so I'll note for the record it is our case
17 of Becton Dickinson and Company, et al versus NeuMoDx, I
18 believe, N-e-u-M-o-D-x, Molecular, Inc., Civil Action No.
19 19-1126-LPS.

20 This is the time we set to hear argument on
21 the remaining pending motions. We've got some things out
22 yesterday that should streamline today's discussion. So we
23 have left the plaintiffs' motion to dismiss with respect to
24 noninfringement as well as the motion especially to strike
25 inequitable conduct.

1 We will hear from plaintiffs first, but any
2 questions before we get started? Any questions from
3 plaintiffs?

4 MR. FLYNN: No, Your Honor.

5 THE COURT: Okay. From defendant?

6 MR. FARNAN: No, Your Honor. Thank you.

7 THE COURT: And I should say I have everybody's
8 slides in front of me that you submitted yesterday so we'll
9 hear from plaintiffs.

10 MR. KAHN: Good morning, Your Honor. This is
11 Omar Kahn for the plaintiffs.

12 The parties have certain screenshots regarding
13 historical background regarding the interaction, why the
14 litigation arose, but we would like to focus our time on
15 the motion to dismiss and strike and specifically on the
16 inequitable conduct issues. With respect to the motion to
17 dismiss on the noninfringement counterclaim, unless the
18 Court has questions we would rest on the papers and the
19 slide.

20 THE COURT: Sure. The only question, you don't
21 oppose giving them leave to amend if I dismiss this version
22 of the noninfringement counterclaim; right?

23 MR. KAHN: Correct. We don't oppose leave to
24 amend.

25 THE COURT: All right. You can focus on

1 inequitable conduct then.

2 MR. KAHN: Thank you, Your Honor. So on the
3 inequitable conduct counterclaims and defenses, this is a
4 case where all NeuMoDx has done is identified statements in
5 the file history with which it disagreed. It is merely
6 challenging those isolated statements made by an attorney in
7 responding to Office Actions that are regarding claim terms
8 and distinction in the prior art. What is not disputed is
9 there is no prior art that was withheld. We know test
10 results that were not provided. There is no relevant
11 internal products that was not disclosed, no prior use
12 on-sale bar information not provided. There is no evidence
13 of contradictory statements made by the attorney internally,
14 in publications or made by BD.

15 All of the underlying information that formed
16 the basis for the attorneys' arguments, here Mr. Israelsen,
17 was before the Examiner. The attorney and Examiner were
18 looking at the same material, going back and forth based on
19 the same materials to which they both had access equally.

20 No case law, not from NeuMoDx, we haven't found
21 any, exists where inequitable conduct allegations was
22 sustained based solely on the statements in the file history
23 and the challenge disagreements with those statements.

24 There is no such case because that would be
25 contrary to the repeated view from the Federal Circuit that

1 inequitable conduct claims are the atomic bomb of patent
2 litigation and a plague to be avoided; and if NeuMoDx's
3 claims were allowed and if attorney argument or advocacy of
4 the type that is present here in this case were sufficient,
5 every single case would involve inequitable conduct claims
6 based on the statements in the file history.

7 To address exactly this issue, this problem, the
8 Federal Circuit has amplified and explained several times
9 what the Rule 9 standard means in this context.

10 So while NeuMoDx might prefer to "kick the can"
11 down the road to summary judgment and post-trial, the
12 controlling Federal Circuit authority instructs that it must
13 satisfy the heightened pleading requirements today; and
14 NeuMoDx has failed to do so because ultimately all that it
15 has put forward in the amended answer are labels and
16 conclusions, not facts to support the inequitable conduct
17 allegations.

18 The cases cited in the briefing are clear that
19 on these very same facts, the same facts presented by this
20 case, issues of claim interpretation, distinguishing the
21 prior art are attorney argument that cannot be the subject
22 of inequitable claims; and even if they could, NeuMoDx
23 separately cannot satisfy the materiality -- knowledge and
24 materiality and falsity and intent to deceive requirement.
25 There is simply no alleged facts, only conclusory

1 assumptions to support those elements.

2 With the Court's permission, I will quickly hit
3 each of those elements: affirmative misrepresentation of
4 fact, but-for materiality, knowledge of falsity of
5 materiality, and intent to deceive.

6 Starting with affirmative misrepresentation. We
7 can start on slide 4.

8 NeuMoDx's first theory relates to the Wilding
9 reference. And, importantly, of course, there is no dispute
10 the Wilding reference was available in the record. In fact,
11 the Examiner was the one that cited the Wilding reference in
12 the first instance.

13 NeuMoDx's theory relates to one sentence in
14 the attorney's response to the Office Action; and NeuMoDx
15 disagrees with the statement that Wilding does not disclose
16 thermocycling the PCR reaction.

17 If we go to slide 5, NeuMoDx had a second
18 disagreement with a different statement again regarding the
19 Wilding reference, but it's really the same theory. The
20 same theory that the prosecuting attorney Mr. Israelsen
21 incorrectly interpreted the content of the prior art Wilding
22 reference.

23 And here, the statement that NeuMoDx disagreed
24 with -- disagrees with is the statement that Wilding does
25 not teach "a multi-lane microfluidic cartridge, each lane

1 comprising a PCR reaction."

2 If we're on slide 6, the only reason to have
3 this slide for the Court is to show that these comments were
4 made in response to a nonfinal Office Action. These are
5 amendment and response to the Examiner's action which is
6 not a declaration or an affidavit which sometimes, under
7 the Federal Circuit's case law, is subject to a slightly
8 different standard.

9 On slide 7, we have started to lay out the
10 Federal Circuit cases that speak directly to this issue.
11 *Young* and *Akzo*, these two cases directly speak to attorney's
12 arguments relating to the decision in the prior art.

13 In *Young*, what the attorney did was to
14 "interpret what the fulsome record teaches and why the
15 decision disclosed in that reference is different from the
16 claim limitation." That is exactly what Mr. Israelsen did
17 in this case.

18 In the *Akzo* case, the applicant argued to the
19 Examiner that prior -- two prior art references did not
20 anticipate the patent, and it cited certain limitations
21 that were not met by prior art. That is exactly what
22 Mr. Israelsen did in this case.

23 If we go to slide 8, these two Federal Circuit
24 cases are arising in a slightly different context, Your
25 Honor. These are cases that don't necessarily relate to

1 distinguishing, to whether or not claim limitations were
2 present in the prior art, but now the attorney is making
3 arguments about whether in the *Life Techs.* case there was a
4 reasonable expectation of success.

5 And in the *Rothman* case, whether the art cited
6 was analogous to the claims and to the patent claims that
7 were being prosecuted.

8 Again, in both cases, the Federal Circuit
9 found that the attorney argument could not give rise to an
10 inequitable conduct claim.

11 And, again, both of these issues, we have
12 related Federal Circuit cases that speak to the fact that
13 reasonable expectation of success as the Court notes is a
14 question of fact. The attorney was arguing about questions
15 of fact, whether or not the reference is prior art. It is
16 analogous. It is also a question of fact. The attorney in
17 *Rothman* was also arguing about questions of fact.

18 On slide 9, we have two industry court cases
19 that apply these teachings from the Federal Circuit.

20 The *SunPower* case in particular is on a 12(b)(6)
21 standard where the defendant sought leave to amend and leave
22 to amend was denied. And in that case, the applicants
23 distinguish the teachings of the prior art in order to
24 traverse a nonfinal rejection. The applicant statements
25 were arguments against a rejection; and the Court held that

1 the challenger could not satisfy, did not satisfy the
2 pleading standard for inequitable conduct.

3 On slides 10 and 11 of the presentation, what
4 we have done is simply cut and paste exactly what the
5 challenged statements are that Mr. Israelsen made in the
6 leftmost column; and then in the two right columns, we
7 cut-and-pasted corresponding statements that the attorney
8 -- the challenged statements that were made by the attorney
9 in some of the cases that we just talked about.

10 And in each instance, the statements are
11 virtually identical. In each instance, the statements are
12 distinguishing the prior art, identifying the limitations
13 that were missing in the prior art, and arguing that the
14 claims were patentable over the prior art.

15 In the *SunPower* case, which is on slide 11, that
16 case is almost directly on point. Again, as I said, that
17 was a 12(b)(6) case where leave to amend was denied.

18 The applicant tried to distinguish what there
19 was a Woodring reference and argued that no known invention
20 suggested by the prior art contemplates the use of
21 photovoltaic modules; and the challenger in the litigation
22 alleged that contrary to the attorney's representation,
23 Woodring does contemplate the use of those modules.

24 And that is exactly the challenge here for the
25 statement made by the Mr. Israelsen.

1 And so with respect to NeuMoDx's first theory
2 based on the Wilding reference, all of the cases are clear
3 that when discussions of the content of the prior art
4 distinguishing the prior art, and arguing that the claims
5 are patentable to the prior art, those are all attorney
6 arguments. They cannot give rise to an inequitable conduct
7 claim.

8 On slide 12, if we can turn to that slide, we
9 have NeuMoDx's second theory which is even worse in our
10 view than the first theory. Because now, it's not even a
11 discussion of the prior art. What here NeuMoDx is starting
12 to challenge relates to an amendment to the patent claims.
13 And here, NeuMoDx challenges the deletion of the term
14 "microdroplet" and Mr. Israelsen's remarks describing those
15 amendments.

16 On slide 13, we've replicated exactly what the
17 amendment was; and one of the many amendments that were
18 made was to delete the term "microdroplet" from the claim
19 limitation.

20 And then on slide 14, we have shown the remarks
21 that were provided. And this is part of the same document;
22 the documents in slide 13 and 14 are part of the same
23 document, the same document that was about 15 pages long.
24 And after the section with the black-lined amendment,
25 Mr. Israelsen submitted remarks but concluded with a

1 boilerplate conclusion section that describes the purpose of
2 the amendments that were not specifically addressed in the
3 foregoing discussion.

4 So right before the excerpt on slide 14, there
5 was a discussion of certain amendments that were made, and
6 then this conclusory statement in the conclusion section
7 is directed to the amendments that were not specifically
8 discussed in the prior section.

9 Again, these comments are not in a declaration
10 or affidavit. And we have highlighted the words "it is
11 believed," because the section is expressly the attorney's
12 opinion and his argument. It cannot be, under any
13 circumstances, a factual misrepresentation because the
14 attorney is saying "it is believed that ..." and then the
15 entire section follows, including the sentence that NeuMoDx
16 challenges, which is the sentence that "these amendments
17 have only been made to increase claim readability, improve
18 grammar and reduce the time and effort required for
19 prosecution."

20 And so the reason that this fares even worse
21 than the Wilding reference theory, and we submit that this
22 theory fails for all the same reasons, but it fares even
23 worse because this is true boilerplate language, and it is
24 boilerplate for at least two reasons:

25 First, it turns clearly from on the face of the

1 document. There is a catchall to discuss any amendment that
2 he didn't specifically discuss in the remarks preceding the
3 conclusion section; and, second, it is also boilerplate
4 because, as we discussed in our briefing, Mr. Israelsen
5 recycled exactly the same language twice when he prosecuted
6 the '308 patent. That is one of the patents that is
7 referenced in NeuMoDx briefs, and so it's boilerplate; and
8 so for that reason, it is even worse when we get to slide
9 15, which under the *Innogenetics* case, the comments made
10 in the *Innogenetics* case were almost identical to the
11 comments that Mr. Israelsen made here where there was a
12 throwaway sentence directed to -- a throwaway boilerplate
13 section that was directed to issues that weren't directly
14 relevant. And the Federal Circuit said: That is just
15 boilerplate. We're not going to find inequitable conduct on
16 that ground.

17 Even if there were some claim interpretation
18 or construction issue with respect to the construction of
19 "microdroplet," that also would not give rise to inequitable
20 conduct allegations. We've shown a case here, the *Masimo*
21 case, which was an in-District case for exactly that point.

22 In slide 16, we have done the same thing that
23 we did in the Wilding theory, which is we put the Israelsen
24 statements side by side with the statements that were
25 challenged in the cases that we just discussed; and the

1 boilerplate language in *Innogenetics* is virtually identical
2 because there, the language, the statement from the attorney
3 was the references do not relate to the invention and
4 further discussion of the same is not necessary.

5 So there, of course, the attorney was talking
6 about the prior art references. Here, the attorney was
7 talking about the amendments to the claims. In both
8 instances, the attorney was saying I don't think there is
9 any reason to discuss in *Innogenetics* the references in
10 this case, the rest of the amendment; and that was, in both
11 instances, at the conclusion of the statements and remarks
12 that were being made.

13 We're on to slides 17 and 18, if we could turn
14 to but-for materiality.

15 On slide 18, and maybe it is worth just a second
16 to talk about the but-for materiality theory that they have
17 on the remarks, the "microdroplet" remark.

18 So the chain of causation, Your Honor, goes
19 something like this, as I understand it. It's the
20 "microdroplet" limitation is removed. The Examiner didn't
21 catch it and didn't understand its importance.

22 He then apparently limited his search to
23 non-microdroplet references. He then apparently did not
24 find any relevant art such as -- and then the defendants
25 identified the Zou references, Z-o-u references.

1 And that chain of causation, there is no factual
2 basis to give rise to a reasonable inference than any of
3 those steps in that causation occurred.

4 THE COURT: All right. Yes. You're running out
5 of time. I've got a couple of questions. I've got to stop
6 you there.

7 MR. KAHN: Sure.

8 THE COURT: What is your contention about why
9 the "microdroplet" amendment was made? Do you dispute that
10 it as a broadening amendment? Do you contend that it was
11 done for grammar? What is your position on that?

12 MR. KAHN: So in our view, Your Honor, the Court
13 does not have to confront that issue in that, even assuming
14 the "microdroplet" limitation, it was incorrect to add --
15 to remove that limitation. It's irrelevant because the
16 issue is whether or not the statements that were made were
17 attorney argument.

18 And to be clear, the Court does not have to
19 agree that it was boilerplate because the other cases
20 discussing attorney argument generally would cover it.

21 In terms of whether the "microdroplet"
22 limitation, whether the removal of that limitation broadened
23 the claims, we think of course it did, because the removal
24 limitation would presumptively broaden the claims in some
25 way.

1 So what Mr. Israelson was saying was that the
2 broadening of the claim does not affect their patentability
3 in that way. And so were the Court to deny the motion, we
4 would certainly contest NeuMoDx's allegation that that
5 statement was false.

6 THE COURT: All right. And then in terms of
7 their contentions about what the attorneys said about
8 Wilding, I think they're saying at least some of it was
9 factual misrepresentations because the attorney said here is
10 something that is in -- or I think more accurately here is
11 something that is not in Wilding when the defendant's view
12 is absolutely those things were in Wilding.

13 I don't expect you to agree with that as a
14 factual matter, but if that is a fair reading of the
15 allegation, can't that be the basis for an inequitable
16 conduct allegation?

17 MR. KAHN: No, Your Honor. The very act of
18 distinguishing the prior art means to speak to the content
19 of the prior art.

20 And so when you say my claims are
21 distinguishable over this reference, you are saying that
22 this reference doesn't have that limitation. And to the
23 extent that there was some dispute or difference between
24 distinguishing the prior art and characterizing the prior
25 art, we disagree that there is. The cases are clear that

1 even talking about what the prior art says will not give
2 rise to claims of inequitable conduct. That is clear from
3 the *SunPower* case.

4 THE COURT: All right. Is there no limit on
5 that? I mean if the prosecuting attorney lies about who is
6 the person listed as the inventor on a prior art patent or
7 intentionally lies about the date on the face of the patent
8 or the title of the patent, I mean things we would all agree
9 objectively are not true just by looking at the prior art
10 patent, is that entirely immune as a matter of law from
11 inequitable conduct liability simply because the Examiner
12 can see for him or herself that it is false?

13 MR. KAHN: We're not saying here, Your Honor,
14 the attorneys are immune from liability; and certainly there
15 are cases from this District that say under certain
16 circumstances the, attorney and the applicant can be liable
17 for alleged -- you know, can -- a claim can be stated
18 against them for inequitable conduct.

19 But in the specific circumstance, you have the
20 difference between attorney argument and an affirmative
21 misrepresentation. In the cases that find that the line
22 between attorney argument has been crossed over and now you
23 are into affirmative misrepresentation, that line in those
24 cases relies on the fact there is some extrinsic evidence
25 that contradicted the statement that was made, that shifted

1 the attorney's statement or the advocacy from their
2 arguments for affirmative misrepresentation. There is other
3 evidence out there not in front of the Examiner that was
4 withheld that now arguably would move from the attorney
5 argument field or space to an affirmative misrepresentation.

6 So in the *Wyeth* case, internal testing data
7 and procedures were withheld that would have informed the
8 Examiner's views as to what the testing data was -- the
9 purported testing data meant.

10 In the *Southco* case, there was a product sample
11 and contradictory statements and other publications that
12 were withheld from the Examiner. And so what --

13 THE COURT: All right. Yes. I'm going to have
14 to stop you. I'll give you a couple minutes for rebuttal,
15 but let me turn now to defendants.

16 Go ahead, please.

17 MR. CLELAND: Yes. Good afternoon, Your Honor.
18 This is James Cleland on behalf of defendants.

19 I'd like to start off with a quote from
20 Magistrate Judge Burke in the *Wyeth Holdings* case because
21 there seems to be a lot of dispute here about the fact that
22 you cannot have an inequitable conduct claim when prior art
23 is in front of the Examiner.

24 And his quote from that case is, "To countenance
25 Wyeth's approach would create a perverse incentive where

1 applicants would be free to falsely characterize such
2 documents but then claim immunity from a later charge of
3 inequitable conduct because the mischaracterized material
4 was before the PTO."

5 There are a number of cases out there. We've
6 cited several of them, including *Wyeth Holdings*, including
7 *Southco*, including *Quest*, including *Apotex*, where the
8 inequitable conduct claim has either survived the 12(b)(6)
9 motion or even prevailed on the merits based upon
10 misrepresentations.

11 In each of those --

12 THE COURT: Yes, let me stop you there. In each
13 of those cases, was there not some information that was also
14 in possession of the party charged with inequitable conduct
15 that was not in front of the PTO?

16 MR. CLELAND: Your Honor, I believe that may be
17 the case. *Southco*, if my memory serves me correctly, was
18 largely based on two representations regarding what the
19 prior art did not teach, much like we have here.

20 I don't recall off the top of my head whether
21 other information factored into that analysis. But in all
22 of these cases, I think with the exception of one, the
23 prosecuting attorney was the "who" in the *Exergen* test,
24 and that person was charged at least partially maybe in
25 combination with the inventor of being the one who

1 committed inequitable conduct based upon at least in part
2 misrepresentations.

3 So, Your Honor, I'd like to just comment very
4 briefly on the background here before I dive into the
5 substance. It will be very brief, because I think a little
6 bit of flavor kind of puts the right frame of mind in place.

7 Back when Handylab was sold, BD brought in a new
8 prosecuting attorney in about 2010, Mr. Israelsen. As soon
9 as he stepped in the door, he immediately pushed the
10 inventors, the inventors who knew the prior art, who knew
11 why they claimed the scope of the claims that they did, and
12 who knew what was in the scope of the prior art and it
13 wasn't. He pushed them out the door. He didn't consult
14 them about claim amendments, he didn't consult them about
15 prosecution, and he immediately laid to waste the entire
16 claim strategy that existed. His goal was to obtain the
17 broadest claims possible, really any means possible.

18 So that really takes us to, I'm going to refer
19 Your Honor to our Slide No. 6 where we lay out a pattern of
20 misconduct here.

21 There are at least four acts that form a basis
22 for that pattern. Two of them are in the '708 patent
23 related to the Wilding reference, and they're two separate
24 incidents. They're two separate representations. The
25 third is the "microdroplet" limitation. The fourth is the

1 continuation of these misrepresentations into the '900
2 patent which is a continuation of the '708 patent.

3 And I think it is important, if you turn to
4 Slide No. 7, to look at the actual language of what
5 Mr. Israelsen said, and in the context of what the Patent
6 Office had done before he made that statement.

7 For instance, relative to the Wilding reference,
8 the applicant had just amended the claim to require
9 thermocycling in an single PCR chamber. And that limitation
10 was amended in the claim that said, okay, you can't do it in
11 multiple reaction chambers for the same lane.

12 Well, if you look at slide 8, and I apologize,
13 it may not have a number on it, it's comparison. Wilding
14 clearly discloses a single reaction chamber with a single
15 meter where PCR occurs, yet Mr. Israelsen focuses his
16 attention on Figs. 4, 5, and 6A where you have to cycle
17 between two reaction chambers to complete the PCR reaction.

18 And the problem is he didn't just stop it,
19 arguing what those figures, Figs. 4, 5, and 6 disclose. He
20 made the affirmative statement that Wilding does not
21 disclose thermocycling in the single PCR reaction zone when
22 in fact it absolutely does, as shown in Figs. 1, 2, and 3.

23 The next instance relates to a representation
24 that was made given the nature of this Wilding disclosure.
25 Again, an affirmative representation where Mr. Israelsen

1 said Wilding fails to disclose, at slide 9, multi-lane
2 microfluidic cartridge where each lane comprises a PCR
3 reaction chamber. And he cited the Examiner to paragraph 39
4 in Figs. 2 and 5 when, if you look at our next slide, it
5 directly -- it's contradicted by the language of Wilding
6 at page -- at paragraph 17 where it says the substrate may
7 comprise a plurality of protection reaction chambers to
8 enable the rapid parallel detection of nucleotide in a
9 mixture. Parallel detection requires parallel lanes.
10 Multiple reaction chambers, multiple lanes.

11 That is a representation as to what is not in
12 the prior art, to take the Examiner off the scent of the
13 102(b) reference that had been asserted against the
14 applicants in the prosecution. We have alleged but-for
15 materiality that Wilding would invalidate the claims. That
16 element is there. Those are clear representations.

17 As for the "microdroplet" limitation which we
18 have listed on slide 11, I think Your Honor noted earlier,
19 it is a clear broadening amendment of the claim language.
20 It was not made to increase claim readability, to improve
21 grammar and reduce the time and effort require those in the
22 art to clearly understand the scope. It was made that so
23 when later this was being litigated, that there would be
24 less of a limitation on claim scope because of prosecution
25 history estoppel, either the claim scope or the Doctrine of

1 Equivalents.

2 It was a sword. It was an affirmative statement
3 to try to obtain broader claim scope, and now it's allegedly
4 boilerplate that plaintiff is attempting to use as a shield.

5 And they really cannot have it both ways here.
6 If you are going to make a statement of the Patent Office
7 and it is wrong, and you have done it for the purposes of
8 patentability, then you have to live with the consequences
9 of that statement.

10 There was some question about how this particular
11 statement is material; and I think what plaintiffs' counsel
12 said actually is not exactly the theory here.

13 The theory is, and as we have stated, that by
14 not mentioning that claim amendment, and instead including
15 different claim amendments that focused the Examiner on
16 those claim amendments, for instance, including the claim
17 amendment of a microfluidic cartridge, it really focused the
18 Examiner's attention on what the Examiner was searching.

19 And here the Examiner went away from focusing on
20 the heaters, which is really what the two Zou patents that
21 we said would have invalidated these claims, those are in
22 paragraphs 17 and 18 of our counterclaims, those two
23 references form the bases for invalidity positions in two
24 IPRs that involve the '708 and the '900 patents.

25 That instead of focusing on the broader scope,

1 the Examiner narrowed to "microfluidic," and neither of the
2 Zou patents mentions "microfluidic." It doesn't include
3 that terminology. It includes the terminology
4 "microfabricated."

5 So if you had "microdroplet," the Examiner in
6 all likelihood would have said, okay, I need to go broader
7 than "microfluidic," but it took him away from that focus
8 and that is problem here.

9 You cannot, you can't justify misrepresentations
10 by saying they're meaningless when they clearly had an
11 impact on what the Examiner did.

12 Turning to slide 13.

13 The representations relative to the '900 patent
14 are similar to those in the '708 patent. So I won't go
15 through and I won't repeat those.

16 The other important thing to note here is that
17 we do have a pattern of misconduct. And the case law,
18 including the *Paragon* case, including the -- let me find
19 it -- including similar cases find that that pattern of
20 misconduct is a strong factor when it comes to intent.

21 And there already is the pleading standard where
22 the Court, this Court has made it very clear in cases like
23 *Wyeth Holdings* that the *Exergen* standard applies where the
24 Court only need reasonably infer that the patent applicant
25 made a deliberate decision to deceive the Patent Office.

1 A pattern of misconduct places that gambit of
2 action, that group of actions into that intent, into that
3 intent prong to satisfy that *Exergen* standard. When you do
4 it once, maybe it can be excused. You do it twice, no; but
5 here four times -- four separate times.

6 And that is not a coincidence, that's a pattern,
7 and it shows an intent to clearly deceive the Patent Office
8 here and try to come up with a claim scope that was way
9 beyond what the patentee was entitled to here.

10 Your Honor, I'll pause there if you have any
11 questions.

12 THE COURT: Sure. Thank you.

13 Isn't it an equally plausible inference that
14 the attorney actually believed what he was telling the PTO?
15 This is what he saw in Wilding, this is what he didn't see,
16 and he knew Examiner was a person of skill and had Wilding
17 in front of him or her?

18 MR. CLELAND: Your Honor, I don't believe that
19 that is possible. And I don't believe that that is the most
20 reasonable inference here for two reasons.

21 No. 1, I think if the prosecuting attorney had
22 simply read Wilding, the first embodiment mentioned in
23 the first figures shown are the embodiment in the figures
24 showing a single reaction chamber, a single PCR reaction
25 chamber. It would have been gross negligence not to read

1 that reference before claiming that the reference did not
2 teach a particular claim element.

3 Secondly, that the same thing applies to that
4 disclosure in paragraph 17. You would have had to
5 completely ignored that, which is gross misconduct, or not
6 read it altogether in order to make that representation,
7 that false representation that the Wilding reference does
8 not disclose that claim limitation and that feature.

9 THE COURT: All right. I didn't have other
10 questions at this point on inequitable conduct. Did you
11 want to say any more about that or did you want to say
12 anything about noninfringement?

13 MR. CLELAND: I don't think -- Your Honor, I
14 think I have completed the argument on inequitable conduct,
15 on noninfringement. The only thing I will note is that we
16 followed I think what has been traditional practice of the
17 District. If the Court believes that that is not sufficient
18 in light of the current set of cases, we would request leave
19 to amend; and that's all that I have to add on that piece.

20 THE COURT: Well, if I were to follow the cases
21 that measure the sufficiency of a counterclaim by the same
22 standards, we would measure a claim for infringement. You
23 could see that he's not met that burden at this point with
24 the operative pleadings; is that right?

25 MR. CLELAND: Your Honor, I think it's fair to

1 say that it is pled in a more cursory manner that doesn't
2 include the type of detail that I think some cases and
3 courts have recently required.

4 THE COURT: All right. Is there anything else
5 you wanted to add for the defendant?

6 MR. CLELAND: Nothing else, Your Honor. Thank
7 you.

8 THE COURT: Okay.

9 MR. CLELAND: Your Honor, I'm sorry. I did have
10 one more item to add.

11 It is in our counterclaims and we included in a
12 number of slides, but we laid out both the materiality and
13 the intent allegations. They are pretty thorough. They
14 are pretty compliant with existing in-District as well as
15 Federal Circuit case law as to what has to be pled in order
16 to satisfy the burden under 9(b) for inequitable conduct.

17 So with that, I will close.

18 THE COURT: Okay. Thank you.

19 A couple minutes for rebuttal, if plaintiffs
20 want.

21 MR. KAHN: Thank you, Your Honor. Just a couple
22 of quick things.

23 I think my colleague on the other side, his
24 argument has demonstrated our point really. I think their
25 theory is a gross negligence theory as I think he said that

1 a couple times. That is exactly the theory that was
2 projected en banc by the *Therasense* case.

3 And on some of the other issues, I think the
4 notion that NeuMoDx -- the defendants here should be able to
5 plead and sustain the NeuMoDx counterclaim is undermined by
6 everything my colleague on the other side was just saying.

7 So everything on the materiality point, for
8 example, that the Examiner would have changed the scope of
9 the prior art searching, that's belied by the fact that the
10 Examiner was not looking for microdroplets before the
11 amendment was made.

12 The suggestion, again, so unfounded,
13 unsupported, no facts, suggests the Examiner would
14 have/could have changed the searching.

15 The suggestion that he would have found the Zou
16 references. There is no allegation in the complaints that
17 the word "microdroplet" is used in the Zou reference. It is
18 not, and that is why.

19 The suggestion that the microdroplet -- the
20 Examiner was deterred from searching because of the term
21 "microfluidic," well, that is exactly what the term -- I
22 think I heard counsel just say, even though it is not in the
23 allegations, it is not in the record, I think I heard
24 counsel just say that is the term used in Zou.

25 So the claim, amended claim uses the term

1 "microfluidic." That's what Examiner was searching on and
2 that is the term that is used in Zou. There is no factual
3 basis whatsoever on which to conclude the but-for
4 materiality that they've laid out here.

5 On the pattern of misconduct, I just don't
6 understand, quite frankly, Your Honor, the suggestion there.
7 Zero plus zero plus zero is still zero. I don't think you
8 can stack insufficient allegations on top of each other and
9 suggest somehow that now they're sufficient.

10 And even if you could, but you can't, the
11 pattern of misconduct, the cases that talk about that talk
12 exclusively about pattern of misconduct with respect to the
13 intent to deceive prong, and even within that prong, talk
14 about pattern of misconduct with respect to the deliberate
15 decision to withhold reference or prior art from the office.

16 So the pattern of misconduct doesn't allow them
17 to evade the obligation to show material misrepresentation,
18 materiality, knowledge of materiality, and all of those
19 other elements of inequitable conduct.

20 With that, Your Honor, if you have no further
21 questions, I'll rest.

22 THE COURT: I have no further questions. Thank
23 you both for the argument. I am prepared now to give you my
24 decision.

25 The motion, of course, is plaintiffs' motion to

1 dismiss the defendant's counterclaim seeking declaratory
2 judgment of noninfringement of the asserted patents as well
3 as to strike the defendant's affirmative defense asserting
4 inequitable conduct and a counterclaim for inequitable
5 conduct.

6 For the reasons I will try to explain, my
7 decision is to grant the motion. I'm granting it both with
8 respect to the noninfringement and the inequitable conduct.

9 Let me talk about noninfringement because there,
10 with respect to the motion to dismiss the counterclaim for
11 noninfringement, that motion is granted, but I am also
12 granting leave to the defendants to amend and try again to
13 state their counterclaim for noninfringement.

14 Basically this part of the motion is not really
15 in dispute. I am informed by, among other things, the
16 *Princeton Digital* case that is cited in the briefing; and
17 while I am certainly not requiring anything like the details
18 one sees in an infringement or noninfringement claim chart,
19 I do think that a defendant attempting to assert a
20 counterclaim of noninfringement has to do more than just
21 simply parrot the statute and say I don't infringe, which
22 is essentially all the defendant has done at this point.

23 So that part of the motion is granted, but
24 defendant has leave to attempt to replead.

25 Of course, our focus today was on the other

1 portion of the motion: The motion to dismiss and/or strike
2 the inequitable counterclaim and affirmative defense.

3 This portion of the motion is also granted.

4 In my view, the defendant has failed to meet
5 the heightened pleading standard for pleading a claim of
6 inequitable conduct. And I say that for sort of I suppose
7 high level general reasons and then some specific reasons.

8 As a general matter, I think what the defendants
9 are alleging here comes within the scope of what the Federal
10 Circuit was talking about in the *Rothman* decision.

11 In *Rothman*, the Federal Circuit in 2009 said:
12 "The law prohibits genuine misrepresentation of material
13 fact," but -- that's my "but" -- "a prosecuting attorney is
14 free to present argument in favor of patentable without fear
15 of committing inequitable conduct."

16 So other than the but, that was a quote, the
17 "but" is implied. And the point, of course, is I think that
18 what the defendants are alleging here falls into the bucket
19 of attorney argument and that the defendants have failed to
20 plead any material factual misrepresentation which could be
21 the basis for an inequitable conduct claim.

22 And I say that about both the "microdroplet"
23 amendment statement that defendant point to as well as all
24 the statements about the Wilding prior art. All of that
25 in my mind falls on the side of attorney argument and,

1 importantly, does not fall into the bucket of material
2 factual misrepresentation.

3 Once I reached those conclusions, I also
4 necessarily reject the argument that there is somehow here a
5 well-pled pattern of misconduct by the prosecuting attorney.
6 I don't see that being pled here at all given that I don't
7 see any singular pleading that adequately alleges
8 inequitable conduct. Really, it is that all of this falls
9 within the scope of acceptable attorney argument, attorney
10 advocacy.

11 With respect to the amendment, I'll just say a
12 little bit more. It is undisputed, as you can see it for
13 instance at slide 13, the amendment was made in the fashion
14 that amendments are typically made in prosecution of the
15 patent, through cross-outs and underlining. There is no
16 ambiguity at all about the strike-out of the claim term
17 "microdroplet" and the Examiner could see that just as
18 clearly as anyone could.

19 The statement that accompanied it is a statement
20 of belief; it is at slide 14, the second paragraph there.
21 And it is not, in my mind, plausibly viewed as a material
22 factual misstatement. It is a characterization of the
23 reasons for the amendments. I don't see any material
24 misrepresentation or falsity that one could find in that.

25 The idea that this was putting the Examiner off

1 the scent or might cause the Examiner not to see what
2 otherwise the defendant would characterize as an obviously
3 broadening amendment, I just don't see those as the types of
4 arguments that get you within the scope of what is a very
5 narrow claim, that is, inequitable conduct. It is not what
6 inequitable conduct is for.

7 The Examiner could read the clear amendment,
8 could decide for him or herself why it was there and whether
9 it affected the patentability of the claims and a statement
10 of belief that also is boilerplate. Importantly, I don't
11 see it, at least in this case, coming close to a basis for
12 being meritorious or a well-pled inequitable conduct claim.

13 And similarly, the statements about the Wilding
14 prior art. Without dispute, the prior art was in front the
15 Examiner. The Examiner could read the prior art every bit
16 as well as the prosecuting attorney.

17 The prosecuting attorney is free to make
18 arguments about what is or is not in that prior art, to
19 characterize the relationship of that prior art to the
20 claims that the prosecuting attorney is prosecuting. That
21 is all within the scope of what is permitted in the course
22 of advocacy in front of the PTO. I am just not at all
23 persuaded that there is a plausible allegation here that
24 what the prosecuting attorney said about the prior art
25 constituted a material factual misstatement.

1 It seems to me that all of the other cases that
2 the defendant has tried to analogize this case to are ones
3 in which the party accused of acting inequitably and
4 committing inequitable conduct had some information that
5 the Examiner lacked perhaps information about experiments or
6 studies that that party had done or that a third party did
7 or about some products that were not in front of the
8 Examiner, what have you.

9 There are all sorts of fact patterns that are
10 out there, but in this case, there is no allegation that
11 the prosecuting attorney knew anything about Wilding that
12 the Examiner didn't know or couldn't know, and I just
13 don't think therefore this is a well-pled allegation of
14 inequitable conduct.

15 To the contrary, there are plenty of cases cited
16 here by the plaintiffs which I think are right on point and
17 support my decision that this is not an inequitable conduct.

18 For example, the *Young* and the *Akzo* decisions
19 from the Federal Circuit, the *SunPower* and *LifeScan*
20 decisions from this court, and even the *Masimo* decision.
21 All of these are consistent with the principles that have
22 persuaded me that the motion here should be granted.

23 I think there probably are other flaws with the
24 pleading, including those identified by the plaintiffs.
25 Materiality, intent to deceive I think are probably not

1 adequately pled, but I said enough and rest my decision on
2 what I have said about the lack of allegations with respect
3 to material misrepresentation.

4 So that is my decision. Are there any questions
5 on that, first from plaintiffs?

6 MR. KAHN: No questions, Your Honor.

7 THE COURT: And from defendant?

8 MR. CLELAND: No questions, Your Honor.

9 THE COURT: All right. Anything else that we
10 should talk about, plaintiffs?

11 MR. KAHN: Nothing from our end, Your Honor.

12 THE COURT: Okay. Defendant?

13 MR. FARNAN: Your Honor, this is Brian Farnan.

14 MR. CLELAND: Your Honor, I'm sorry. No.

15 THE COURT: That's a "no" for the defendants?

16 MR. CLELAND: Yes, Your Honor. "No."

17 THE COURT: Okay. Okay. Well, thank you all
18 very much. Stay safe. Thanks for the argument. Good-bye.

19 (Telephone conference ends at 2:26 p.m.)
20

21 I hereby certify the foregoing is a true and accurate
22 transcript from my stenographic notes in the proceeding.

23 /s/ Brian P. Gaffigan
24 Official Court Reporter
25 U.S. District Court

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